K080411

Life Spine®

510(k) Summary
PLATEAU® Spacer System

MAY 15 2008

Submitted By: Life Spine
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510(k) Contact: Rebecca Brooks
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Date Prepared: February 14, 2008

Trade Name: PLATEAU® Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, 21 CFR 888.3080, Class II

Device Description:

The Plateau Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from either Polyetheretherketone (PEEK-OPTIMA LT1) with titanium markers. The implant is hollow to permit packing with bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to prevent rotation and/or migration.

Intended Use of the Device:

The Plateau Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine.

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Performance Data:
Biomechanical testing in accordance with ASTM standards was conducted to demonstrate substantial equivalence to the predicate intervertebral body fusion devices.

Substantial Equivalence:
The Plateau Spacer System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Life Spine
% Ms. Rebecca Brooks
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Hoffman Estates, IL 60169

MAY 15 2008

Re: K080411
Trade/Device Name: PLATEAU™ Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: February 14, 2008
Received: February 15, 2008

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

Indications for Use

510(k) number (if known): K080411

Device Name: PLATEAU® Spacer System

The Plateau Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden for mam

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080411

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